# 510(K) SUMMARY

AUG 10 2007

***Subject 510(k) Number*** K071520

***Sponsor***

Core Essence Orthopaedics, LLC

301 Oxford Valley Road
Suite 905B
Yardley, PA 19067

***FDA Establishment Registration Number***

3004613836

***Official Contact***

Shawn T. Huxel, CEO & President
Core Essence Orthopaedics, LLC
301 Oxford Valley Road
Suite 905B
Yardley, PA 19067
Phone - (215) 310-9534
Fax - (609) 482-4957
Mobile - (908) 896-5893

***Proprietary Name***

reNOVO™ Suture Anchor System

***Common Name***

Suture Anchor

***Classification Name and Reference***

Sec. 888.3040 Smooth or threaded metallic bone fixation fastener

***Regulatory Class***

Class II

***Device Product Code/Subsequent Code***

(Panel 87) MBI/GAT

***Date Prepared***

9 August, 2007

***Brief Description of Device***

The reNOVO™ Suture Anchors range in size from 2.0mm to 5.5mm in diameter.

The anchor portion consists of a threaded titanium (ASTM F136/ ISO 5832-3) segment that provides a self drilling and self tapping thread. The anchor eyelet provides a means to attach the range of suture sizes utilized on the anchors. The size of sutures used in the reNOVO line range from size 3-0 thru size 2 (USP) nonabsorbable UHMW polyethylene UltraFibre™ sutures. A single use driver and handpiece hold the excess suture and deliver the preloaded anchor into the bone. The suture strands are used to reapproximate and secure the soft tissue to the bone.

The reNOVO™ Suture Anchor will be provided sterile for single use applications.

The sizes and materials are designed to address the indications cited.

### *Indications for Use*

reNOVO Suture Anchors are intended to secure soft tissue to bone of:

The Shoulder:
- Bankart Repair
- SLAP Lesion Repair
- Acromio-Clavicular Separation
- Roatator Cuff Repair
- Capsule Repair
- Biceps Tenodesis
- Deltoid Repair

The Elbow:
- Ulnar or Radial Collateral Ligament Reconstruction
- Bicep Tendon Reconstruction
- Tennis Elbow Repair

The Hand and Wrist:
- Scapholunate Ligament Reconstruction
- Ulnar / Radial Collateral Ligament Reconstruction
- Collateral Ligaments around the PIP, DIP and MCP Joints
- Flexor and Extensor Tendons

The Ankle and Foot:
- Lateral Stabilization
- Medial Stabilization
- Achilles Tendon Repair / Reconstruction
- Hallux Valgus Reconstruction
- Mid and Rear Foot Reconstruction

### *Basis for Substantial Equivalence*

The substantial equivalence of the reNOVO Suture Anchors is based on the equivalence in intended use, materials, operational principals, and indications to:

| Mitek | Zimmer | Arthrotek | Arthrex | Smith & Nephew | United States Surgical |
|---|---|---|---|---|---|
| K962511 | K962397 | K012503 | K971723 | K053344 | K040594 |
| K962793 | K926384 | K973775 | K960516 | K972326 | |
| K982420 | | K943806 | | | |

In conclusion: Core Essence Orthopaedics reNOVO suture anchors are substantially equivalent to the currently marked devices and present no substantial differences in design, material, intended use and function to the products on the table above.

***END OF 510(K) SUMMARY***

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Core Essence Orthopaedics, LLC
% Mr. Shawn T. Huxel
CEO & President
301 Oxford Valley Road
Suite 905B
Yardley, PA 19067

AUG 10 2007

Re: K071520
Trade/Device Name: reNOVO™ Suture Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, HWC, JDR
Dated: June 1, 2007
Received: June 4, 2007

Dear Mr. Huxel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or 240-276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510 (K) NUMBER IF KNOWN: **K071520**

MANUFACTURER: Core Essence Orthopaedics, LLC

DEVICE NAME: reNOVO Suture Anchors

reNOVO Suture Anchors are intended to secure soft tissue to bone of:

The Shoulder:
- Bankart Repair
- SLAP Lesion Repair
- Acromio-Clavicular Separation
- Roatator Cuff Repair
- Capsule Repair
- Biceps Tenodesis
- Deltoid Repair

The Elbow:
- Ulnar or Radial Collateral Ligament Reconstruction
- Bicep Tendon Reconstruction
- Tennis Elbow Repair

The Hand and Wrist:
- Scapholunate Ligament Reconstruction
- Ulnar / Radial Collateral Ligament Reconstruction
- Collateral Ligaments around the PIP, DIP and MCP Joints
- Flexor and Extensor Tendons

The Ankle and Foot:
- Lateral Stabilization
- Medial Stabilization
- Achilles Tendon Repair / Reconstruction
- Hallux Valgus Reconstruction
- Mid and Rear Foot Reconstruction

Prescription Use X AND/OR Over-The-Counter Use Y
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ouellet for MJM

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**



**510(k) Number** K071520